

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**Applicant: Hayes *et al.*

Title: Use of Biologically Active Vitamin D Compounds for the Prevention and Treatment of Inflammatory Bowel Disease

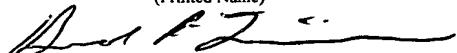
Appl. No.: 10/036,819

Filing Date: 12/21/2001

Examiner: S. N. Qazi

Art Unit: 1616

CERTIFICATE OF MAILING
 I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below.

Bernard P. Friedrichsen
 (Printed Name)

 (Signature)

August 25, 2004
 (Date of Deposit)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO-1449 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR § 1.97(c)(2), and before the mailing date of any final office action, notice of allowance, or other action that closes prosecution of the application. The Commissioner is hereby authorized to charge the fee of \$180.00 (Fee Code 1806) set forth in 37 CFR § 1.97(c)(2) and § 1.17(p) to Deposit Account No. 50-2350 for such purpose. The listed documents were cited in an International Search Report (ISR) dated August 11, 2004, for a related PCT application. A copy of the ISR is enclosed. The other documents listed in the ISR were previously reported to the United States Patent and Trademark Office for this application.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-1449 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-2350. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-2350.

Respectfully submitted,

Date August 25, 2004

By 

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Form PTO-1449

(MODIFIED)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

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APPLICANT

Hayes et al.

FILING DATE

12/21/2001

GROUP ART UNIT

1616

INFORMATION DISCLOSURE CITATION

O I P E J C T 186
AUG 30 2004
P A T E N T & T R A D E M A R K O F F I C E
Please several sheets if necessary

U.S. PATENT DOCUMENTS

| EXAMINER INITIAL | REF | DOCUMENT NUMBER | DATE | NAME | CLASS | SUB-CLASS | FILING DATE IF APPROPRIATE |
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FOREIGN PATENT DOCUMENTS

| | REF | DOCUMENT NUMBER | DATE | COUNTRY | CLASS | SUB-CLASS | TRANSLATION | |
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OTHER DOCUMENTS (*Including Author, Title, Date, Pertinent Pages, Etc.*)

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| | | DeLuca, Hector et al., "Vitamin D: Its Role and Uses in Immunology," <i>The FASEB Journal</i> , 2001, Vol. 15, pp. 2579-2585. |
| | | Breese, E. et al., "Interleukin-2- and interferon-gamma-secreting T cells in normal and diseased human intestinal mucosa," <i>Immunology</i> , 1993, Vol. 78, pp. 127-131. |
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EXAMINER

DATE CONSIDERED

* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.